REMARKS

Claims 38-43 are now pending. Claim 38 has been amended to define the polypeptide as SEQ ID NO: 2 and to define the composition as "an immunogenic composition" instead of "a vaccine." The composition has also been amended to include a cancer treating effective amount of the polypeptide. Support for this amendment is found, for example, in claim 39, and Figure 1. Applicants affirm the election of claim 38 and acknowledge the Examiner's indication that claim 39 will be rejoined upon allowance of claim 38 from which it depends. Support for new claim 40 is found in original claim 38. Support for new claims 41, 43 and 44 is found, for example, in Figure 2A. Support for new claim 42 is found, for example, on page 35, last two paragraphs.

The specification has been amended in the Preliminary Amendment filed January 16, 2004, to address the objections recited on page 5 of the Office action. The specification has been further amended herein to address the Office's objections to references to http, www and HERCEPTIN®.

Applicants traverse the rejection of claim 38 under 35 U.S.C. § 112, first paragraph (enablement). The test of enablement is whether a person of skill in the art could make and use the claimed invention from the patent's disclosure, coupled with information known in the art, without undue experimentation. *See United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ.2d 1217, 1222 (Fed. Cir. 1988). It is well settled law that "a patent need not teach, and preferably omits, what is well known in the art." *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

Applicants respectfully submit that the application contains sufficient disclosure to enable a skilled artisan to practice the claimed invention. Figure 3C, for example, shows mRNA expression in prostate cancer xenographs in comparison with normal cells. Further, Figure 4A shows high expression of mRNA in other cancer cell lines in addition to prostate cancer xenographs. High expression was also found in cancer cell lines as shown in Figure 4B and as described on page 29, lines 16-17 of the present specification. Further, applicants respectfully

submit that immunization techniques are known in the art as described in the present specification on page 35, lines 24-27, as well as page 36. Therapeutic strategies are described in the present application on pages 58-60 and cancer vaccines are directed on pages 60-62. Using a tumor antigen for anticancer therapy is well known in the art as described on page 60, lines 10-14 of the present application, for example. Thus, the specification provides sufficient guidance for invoking an anticancer or immunotherapeutic response, and provides guidance on the administration of the claimed composition as such uses are known in the art. The Office has not pointed to any deficiency in the specification which would indicate that one following the directions in the specification would be unable to make and use the claimed composition. Absent such a showing, the statements in the specification should be taken at face value and the full scope of the claimed invention recognized. *In re Marzocchi*, 439 F2d 220, 169 USPQ 367 (CCPA 1971).

The Office cites Bodey, *et al.,* to support its argument for lack of enablement. However, Bodey discloses dendritic cell vaccines, which are unrelated to the proteins as presently claimed. With regard to Bellone, *et al.,* also cited by the Office, the disadvantages of amino acid therapy that are allegedly presented therein do not provide any evidence that the claimed peptide may not be made and used. Gaiger, *et al.,* , also cited by the Office, describes a Wilms tumor antigen, which is not related to the claimed peptide. Thus, the Office has not established that a skilled artisan would be unable to make or use the composition as claimed.

Applicants traverse the rejection of claim 38 under 35 U.S.C. § 112, first paragraph (written description). Applicants gratefully acknowledge the Examiner's indication that SEQ ID NO: 2 meets the written description requirement. Claim 38 has been amended to recite the composition comprising such amino acid sequence. Thus, this rejection may be properly withdrawn.

Applicants traverse the rejection of claim 38 under 35 U.S.C. § 102(e) as being anticipated by Baker. The provisional application upon which the Baker publication claims priority, namely 60/104,987, filed on October 20, 1998, does not disclose immunogenic compositions as claimed and does not disclose overexpression in any cells. In contrast, U.S. provisional application

No. 60/128,860 upon which the present application claims priority was filed April 12, 1999 and discloses overexpression in prostate cancer cells and immunotherapy. Thus, it is respectfully submitted that Baker may not be used as a reference against the present claims.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 511582001310. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

By _____

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